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Registration Decision RD2012-30

Ammonium Bromide Fuzzicide

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Registration Decision for Ammonium Bromide (Fuzzicide)

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Fuzzicide (Ammonium Bromide) and Fuzzicide Solution, containing the technical grade active ingredient ammonium bromide.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2012-08, *Ammonium Bromide Fuzzicide*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for ammonium bromide fuzzicide and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2012-08, *Ammonium Bromide Fuzzicide*. This decision is consistent with the proposed registration decision stated in PRD2012-08, *Ammonium Bromide Fuzzicide*.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2012-08, *Ammonium Bromide Fuzzicide* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Ammonium Bromide?

Ammonium Bromide is the active ingredient in Fuzzicide (Ammonium Bromide) at a concentration of 99% and the end-use product Fuzzicide Solution at a concentration of 35%. Fuzzicide Solution is used as a slimicide in pulp and paper mill whitewater systems and starch slurries. Fuzzicide Solution is used with sodium hypochlorite to produce the active biocide, Fuzzicide biocide, which is the active biocide that prevents the presence of undesirable organisms.

Health Considerations

Can Approved Uses of Ammonium Bromide Affect Human Health?

Ammonium bromide is unlikely to affect your health when used according to the label directions.

When assessing health risks, the PMRA considers two key factors: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). The risk assessment is conducted to ensure that the level of human exposure is well below the lowest dose at which effects occurred in animal tests. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose at which no effects are observed. Some of the toxicology studies routinely required to register a pesticide were not available for ammonium bromide. However, because exposure was determined to be negligible for the use on pulp and paper, no further studies were requested. For any future use expansions, however, the PMRA will reconsider the need to address data gaps.

The technical grade active ingredient ammonium bromide caused mild eye irritation in animals and showed the potential to cause acute health effects in animals when it was inhaled. Consequently, the statement "Caution—Poison, Eye Irritant" is required on the label as well as the skull and crossbones symbol. Health effects in animals given daily doses of ammonium bromide over short periods (4 weeks to 3 months) included clinical signs of toxicity, decreased body- and organ-weights as well as effects on blood and urine. Although ammonium bromide was not tested to see if it causes cancer, it was not found to be genotoxic. Ammonia on its own, however, has been found to cause some forms of genotoxicity. Some effects were noted on the nervous system, including clinical signs of toxicity, behavioural effects and some indications of effects on nervous tissue. When ammonium bromide was given to pregnant animals, effects on the developing fetus and on offspring were observed at doses that were not toxic to the mother, indicating that the fetus or young animal was more sensitive to ammonium bromide than the adult animal. Effects on reproduction were also seen, but at doses that were toxic to adult animals.

Studies conducted with sodium bromide were also provided to supplement the ammonium bromide toxicology database. When given to pregnant animals, sodium bromide caused effects on offspring at doses that were also toxic to the mother. Effects on reproduction were seen at doses that were toxic to adult animals. Other effects on adult animals included decreased thyroid-hormone levels, decreased body weights and organ weights as well as effects on blood at very high doses.

Risks in Residential and Other Non-Occupational Environments

Estimated risk for non-occupational exposure is not of concern when directions specified on the label are observed.

Residential exposure to individuals contacting treated paper is not expected to result in unacceptable risk when Fuzzicide Solution is used according to label directions.

Occupational Risks From Handling Fuzzicide Solution

Occupational risks are not of concern when Fuzzicide Solution is used according to the label directions, which include protective measures.

Due to the requirement for closed loading and transfer of Fuzzicide Solution, workers mixing and loading the product are not expected to have direct contact with Fuzzicide Solution. In addition, the label will specify that anyone mixing or loading Fuzzicide Solution must wear face protection, a long-sleeved shirt and long pants, chemical-resistant gloves and chemical-resistant footwear. Taking into consideration these label requirements, risk to workers handling Fuzzicide Solution is not of concern.

For postapplication workers in pulp and paper facilities, exposure to bromide in the re-circulating water following the use of Fuzzicide Solution is not expected to be greater than the exposure to bromide from currently registered products.

Environmental Considerations

What Happens When Fuzzicide Biocide Is Introduced Into the Environment?

Fuzzicide biocide is toxic to freshwater alga and vascular plants and to both freshwater and marine invertebrates and fish; therefore, label instructions are required to protect these organisms and to minimize exposure to the aquatic environment.

Fuzzicide Solution has to be reacted with a 12.5% aqueous solution of sodium hypochlorite to form the active biocide, Fuzzicide biocide or bromide-activated chloramine (BAC). Fuzzicide biocide has the potential to enter into the environment when used as a slimicide in pulp and paper mills. This active biocide is not persistent in the aquatic system and is rapidly degraded to substances such as ammonia/ammonium, nitrate, chloride, bromide, bromoform and chloroform which are already found in natural and effluent waters. With the exception of ammonium, the transformation products of BAC are not expected to adsorb to sediment. Under actual use conditions in an operational pulp and paper mill, Fuzzicide biocide concentrations were below the detection limit (0.05 mg Cl_2/L) at the point of discharge into the watercourse. Soil is not expected to be exposed to Fuzzicide residues; therefore, these residues are not expected to be found in the terrestrial environment.

Based on the specific use pattern for Fuzzicide Solution in pulp and paper mills, Fuzzicide biocide presents a negligible risk to aquatic organisms. Specific statements regarding its toxicity to aquatic organisms and statements to minimize exposure to the aquatic environment are provided on the product label.

Value Considerations

What Is the Value of Fuzzicide Solution?

Fuzzicide Solution is a slimicide for use in pulp and paper mill whitewater systems and starch slurries. Fuzzicide Solution is used with sodium hypochlorite (12.5%) via the Fuzzicide feeder/delivery system to produce Fuzzicide biocide. This product is a new alternative slimicide that can be used to prevent the fouling of whitewater systems and starch slurries caused by bacterial, fungal and algal contamination that have been known to result in loss of productivity in pulp and paper mills.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Fuzzicide Solution to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

To avoid direct contact with ammonium bromide on the skin, only closed loading and transfer is permitted for Fuzzicide Solution. In addition, anyone handling Fuzzicide Solution or contacting treated process fluids must wear face protection, a long-sleeved shirt and long pants, chemical-resistant gloves and chemical-resistant footwear.

Environment

Fuzzicide biocide is toxic to freshwater alga, vascular plants, freshwater and marine invertebrates as well as to fish; therefore, specific statements to minimize exposure to the aquatic environment are provided on the product label.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2012-08, *Ammonium Bromide Fuzzicide)* are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act.*